decreasing from 65% in 2005 (n=17) to 47% in 2013 (n=15) but then drastically improving to 82% in 2014 (n=22). The BNF category with the highest recommendation rate was infections (88%, n=102); conversely, the gastro-intestinal system category had the lowest recommendation rate (55%, n=42). **CONCLUSIONS:** Results suggest that HTA trends in Scotland were reformed in 2014 by changes in the SMC process, which included the aim of improving patient access to cancer medications. Recent changes implemented by SMC as a result of the Routledge review may provide hope to companies preparing to navigate the SMC process with oncology, immunology or infection products, but companies with products in other areas should explore all considerations through further analyses to maximise market access opportunities in Scotland.

PHP139

TRENDS IN THE USE OF COST-MINIMIZATION ANALYSIS IN ECONOMIC ASSESSMENTS SUBMITTED TO THE SMC

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OBJECTIVES: The Scottish Medicines Consortium (SMC) recommend the use of cost-minimization analysis for: therapeutically equivalent treatments established through non-inferiority studies; indirect comparisons showing statistically insignificant difference; or where cost-utility analysis shows extremely small quality-adjusted life year differences between treatments. When a new medicine has identical benefits to the comparator, the SMC chooses the cheaper option. In 2014, the Office for Health Economics found that whilst the SMC does not specify a type of economic analysis for biosimilars, cost-minimization analysis had been used for all approved submissions. We examine longitudinal trends and probabilities of recommendation for any companies using cost-minimization analysis. **METHODS:** All analyses were based on a validated, longitudinal database of all recommendations from 2002 to 2014. SMC recommendations following full submission, resubmissions or abbreviated submissions were reviewed to provide some insight into the considerations that companies should include in their strategic plans. **RESULTS:** Since 2010, there has been an increasing trend for the use of cost-minimization analysis with 35% of full submissions in 2014 using cost-minimization, as well as 25% of resubmissions. Of the 68 cost-minimization submissions, 24 have received positive recommendation, 35 restricted and 9 not recommended. Cost minimization has been used in the greatest proportion of respiratory submissions (47% of submissions, n=8, 88% recommended) and infections (43% of submissions, n=6, 100% recommended) but most cost-minimization submissions are for endocrine treatments (30% of submissions, n=11, 91% recommended). The recommendation rates per BNF category vary greatly with no distinct category having greater success. **CONCLUSIONS:** A manufacturer is most likely to gain a restricted recommendation following submission of cost-minimization analysis. There is no distinct BNF category that has a greater chance of success using cost-minimization analysis. To recommend with cost-minimization analysis, the SMC must be certain that the comparators are appropriate and effectiveness is comparable.

PHP140

ASSESSING THE QUALITY OF HEALTH ECONOMIC EVALUATIONS PUBLISHED IN JAPANESE SETTIGNS: A SYSTEMATIC REVIEW OF 1991-2012 LITERATURE

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OBJECTIVES: Considering official introduction of pharmacoeconomic requirements in Japanese healthcare policy in 2016, we aimed to assess whether the quality of pharmacoeconomic studies in Japan has been improved over time, and what aspects are in need for further improvement. **METHODS:** The literature review approach was taken for English-language articles via PubMed (Japan AND "Cost-Benefit Analysis"[Mesh]) and Embase (Japan AND cost effectiveness), and also for Japanese-language via Web service of Japan Medical Abstracts Society ("hiyo-tai-koka" in Japanese, which means "cost-effectiveness"), excluding review articles, commentaries, methodological studies, and letters. After eligibility screening, we eventually obtained 174 articles as subjects, which were summarized and assessed regarding the quality of reporting on whether to state the five factors explicitly: 1) study perspective, 2) reason of discount rate, 3) year of currency, 4) time horizon, and 5) comparator. For each of those factors, we examined a proportion of satisfaction, i.e., a percentage of the articles having clearly described the target factor among all the articles. In addition, the proportions were compared by the other nominal factors such as founding source, intervention type, and QALY employment. **RESULTS:** The number of publications has been increasing over time. Over 60 % of studies, however, did not clearly disclose their funding sources. The studies without any funding disclosure revealed less satisfaction in each of the five factors. Those with disclosure of industry-funding had higher satisfaction rates compared to the studies with public-funding disclosure or without funding disclosure. Although the studies which employed QALY as the outcome measure earned high satisfaction of the five factors, no totally positive improvement was observed over time in terms of satisfaction for any of the five factors. **CONCLUSIONS:** The quality of reporting the Japanese health economic evaluations was not yet satisfactory, and remains further challenges for quality improvement to comply with the international standards.

PHP141

ROLE OF INDIRECT COMPARISONS IN THE AMNOG EVALUATION PROCEDURE

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OBJECTIVES: The AMNOG assessment procedure requires that manufacturers submit indirect comparisons for the assessment of molecules in the absence of direct comparisons versus the G-BA appropriate comparator. The purpose of this study was to understand the role that indirect comparisons have in IQWiG's assessment of added benefit and consequently also on the G-BA decision outcome. **METHODS:** The IQWiG assessments and G-BA evaluations through the AMNOG process from initial implementation to the end of 2014 were analyzed based on publications from the G-BA website. 104 molecules that had gone through the AMNOG procedure were identified and further categorized in order to determine whether they had submitted direct, indirect, or both types of comparisons. The G-BA publications by means of the classification score were used to source and quantify the outcome of the decision. **RESULTS:** 16 out of the 104 analyzed molecules were found to have submitted indirect comparisons. Out of these, the G-BA decisions recognized that 6 molecules had mild or significant overall added benefit. All of these 6 molecules presented both direct and indirect comparisons. On the other hand, molecules that only submitted indirect comparisons were found to have no additional benefit. The most common reasons for dismissals of indirect comparisons by IQWiG were the inappropriate patient population selection, the choice of inappropriate bridge comparators, and that population uniformity was not guaranteed. **CONCLUSIONS:** These results demonstrate that submission of indirect comparisons alone are unlikely to result in a positive added benefit classification by IQWiG and the G-BA. However, if the indirect comparison is coupled with a direct comparison, the outcome of the assessment by the G-BA is more likely to result in a positive added benefit classification.

PHP142

TREND ANALYSIS OF G-BA DECISIONS – WHAT FACTORS INFLUENCE THE LIKELIHOOD OF RECOMMENDATIONS?

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OBJECTIVES: The first step in the route to reimbursement of a new product in Germany through the Arzneimittelmarkt-Neuordnungsgesetz (AMNOG) process is an assessment of additional benefit, conducted by the Gemeinsamer-Bundesausschuss (G-BA), which directly influences pricing negotiations. The G-BA may classify additional benefit of a new substance as major, considerable, minor or unquantifiable benefit or 'no-benefit'. The analysis was conducted to compare trends of G-BA decisions for new technologies and orphan technologies. Further analysis was conducted to identify differences in disease areas for companies planning a European launch of a new product. **METHODS:** A longitudinal database containing all additional benefit decisions made by the G-BA was analyzed. Only one decision was published in 2011 so only data from 2012-2014 was explored for robustness. Orphan analysis was conducted for products with European Union (EU) orphan designation. Analysis by disease area classified products into British National Formulary (BNF) categories. **RESULTS:** In 2012-2014, G-BA assessed 99 new technologies and decided 48% of products had no additional benefit, 25% had minor additional benefit, 18% had considerable additional benefit and the remainder had unquantifiable additional benefit. No technologies have been classified as having major additional benefit. G-BA are unable to classify an orphan treatment has having no additional benefit due to the nature of orphan designation thus no 'no-benefit' decisions of orphan products have been made but the G-BA decided that 38% (n=16) of orphan products had unquantifiable benefit and 19% had considerable benefit (n=3). 34% of decisions were for malignant disease and immunosuppression products. 12 of the 19 products found to have considerable benefit were for malignant disease and immunosuppression. **CONCLUSIONS:** A high proportion of G-BA decisions have been of no or unquantifiable benefit indicating that obtaining a high price in Germany is challenging but more likely for orphan, malignant disease and immunosuppression products.

PHP143

ANALYSIS OF HEALTH TECHNOLOGY ASSESSMENT REQUIREMENTS IN 7 ASIA OCEANIA COUNTRIES/REGIONS: COMPARISON OF EVIDENTIARY REQUIREMENTS FOR STANDARD AND ORPHAN DRUGS

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OBJECTIVES: Information regarding health technology assessment (HTA) requirements for orphan drugs in Asia Oceania is limited. The aim of our study was to compare HTA evidentiary requirements for standard and orphan drug appraisals among 7 Asia Oceania countries/regions. **METHODS:** A literature and policy review was conducted to identify standard and orphan drug HTA requirements and processes for the following countries: Australia, Japan, South Korea and China (further divided into regions including Mainland China, Hong Kong, Singapore and Taiwan to capture the diverse healthcare markets included in the country). A modified Hutton Framework was used to descriptively assess the HTA and reimbursement processes in these 7 countries/regions. **RESULTS:** Authorities in Asia Oceania are currently in various stages of HTA and reimbursement process development for standard and orphan drugs. Of the 7 countries/regions studied, Australia is the only country with distinct orphan drug HTA evidentiary requirements and processes compared to standard drugs. Cost-effectiveness evidence is required as part of South Korea's standard HTA review, but incremental cost-effectiveness ratio (ICER) thresholds are more lenient for orphan drugs. In Hong Kong, orphan drugs are assessed by an independent expert review committee, and appraisal criteria weigh heavily on patient characteristics and perceived benefit. Several countries/regions include health economics in their standard HTA review: Taiwan (budget impact, comparative effectiveness) and Singapore (cost-effectiveness); both countries/regions have similar evidentiary requirements for orphan and standard drugs. Japan is in early stages of developing HTA procedures and requires minimal economic evidence in standard and orphan drug assessment. Mainland China does not have a centralized HTA process for standard and orphan drugs. **CONCLUSIONS:** Most Asia Oceania countries/regions are still developing their HTA policies. Due to lack of distinct orphan drug HTA procedures in Taiwan, Singapore, Mainland China, and Japan, obtaining reimbursement for drugs may require additional efficacy or health economic analyses.

PHP144

TRENDS IN HEALTH TECHNOLOGY ASSESSMENT (HTA) RECOMMENDATIONS FROM THE UK AND GERMANY â€“ A COMPARISON OF G-BA, SMC AND NICE SINGLE TECHNOLOGY APPRAISAL DECISIONS

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